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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED, Plaintiff, v. VYSIS, INC., Defendant.	CASE NO. 99CV 2668H (AJB) **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF VYSIS' MOTION FOR ENTRY OF FINAL JUDGMENT UNDER RULE 54(b)** Date: July 30, 2001 Time: 10:30 am Dept.: Courtroom 1

On June 19, 2001, this Court granted Gen-Probe's motion for partial summary judgment under Counts One and Three of its Second Amended Complaint that its nucleic acid test for human immunodeficiency virus ("HIV") and hepatitis C virus ("HCV") does not literally infringe the claims of Vysis' U.S. Patent No. 5,750,338 ("the '338 patent"). In granting Gen-Probe's motion, the Court construed the claims of the '338 patent as encompassing only non-specific amplification methods.

Vysis has carefully reviewed the Court's ruling and concludes that (1) the Court erred in construing the claims more narrowly than their legally correct scope, (2) Vysis has no reasonable expectation of prevailing at trial on the issue of infringement if the Court's claim construction is sustained, and (3) any attempt to resolve patent validity and enforceability issues using the Court's narrow claim construction will be a waste of resources of the Court and the parties. If Vysis is correct and the claims are determined by the Federal Circuit to be of broader scope, the validity and enforceability issues will have to be retried. If Vysis is incorrect and the Court's narrow claim construction is sustained on appeal, there will be no need to try the validity and enforceability issues at all. Accordingly, Vysis seeks entry of final judgment against it on Counts I and III of Gen-Probe's Second Amended Complaint pursuant to Rule 54(b), Fed. R. Civ. P. and a stay of all remaining proceedings, so that it may pursue an immediate appeal of this core claim construction issue to the Federal Circuit.

I. Entry of Final Judgment is Appropriate

When a lawsuit involves multiple claims for relief, Rule 54(b) permits the Court to enter final judgment as to fewer than all of the counts upon an express determination that there is no just reason for delay. Fed. R. Civ. P. 54(b).[1] As no just reason for delay exists here, this case is a perfect candidate for entry of final judgment as to Gen-Probe's Counts I and III.[2]

A. The Court's Summary Judgment Ruling is Dispositive

The Court's claim construction and summary judgment grant, if sustained on appeal, are finally dispositive of Count I of Gen-Probe's Second Amended Complaint. Moreover, although the Court did not make an express declaration of Gen-Probe's rights and obligations under its license with Vysis, the Court's holding that Gen-Probe's HIV/HCV test kit does not infringe the claims of

[1] Fed. R. Civ. P. 54(b) uses the term "claim" to refer to a "claim for relief." To avoid confusion between the different usages of the word "claim" in civil procedure and patent law, this Memorandum will, unless otherwise indicated, use the term "count" to refer to a "claim for relief" and the term "claim" to refer to the claim of a patent.

[2] Count I of Gen-Probe's Second Amended Complaint alleged that its HIV and HCV test kits do not infringe the claims of the '338 patent. Count III sought a declaration of Gen-Probe's rights and obligations under its license with Vysis. Second Amended Complaint, ¶¶ 27-28, 31-33 (attached as Exhibit A to the Declaration of Thomas W. Banks in Support of Vysis' Motion for Entry of Judgment Under Rule 54(b) ("Banks Decl.").)

the '338 patent, if sustained on appeal, necessarily disposes of Count III.[3] The basic foundation of Gen-Probe's lawsuit is "the nature and scope of any obligation of [Gen-Probe] to make royalty payments to [Vysis]" pursuant to the parties' '338 patent license agreement. (Gen-Probe Second Amended Complaint, ¶ 1 (Banks Decl. Exhibit A).) The Court's summary judgment ruling effectively resolves this issue.

B. Trial of the Invalidity and Unenforceability Counts Will be Wasteful

The Court's summary judgment of noninfringement necessarily resolves Gen-Probe's rights and obligations under the '338 license. Accordingly, there is nothing further for Gen-Probe to gain by trying the issues of invalidity (Count II) and unenforceability (Counts V and VI). Indeed, proceeding with trial of those issues after ruling on summary judgment that there is no infringement as a matter of law would effectively result in rendition of an impermissible advisory opinion concerning the validity and enforceability of the '338 patent.

Moreover, the Court's claim construction ruling is central to and will affect the discovery and trial of all of the patent issues remaining in this case. Gen-Probe has asserted that the claims of the '338 patent are anticipated under 35 U.S.C. § 102 and obvious under 35 U.S.C. § 103. Resolving each of these issues will require comparing the *claimed* invention against the prior art. *See, e.g., SIBIA Neurosciences Inc. v. Cadus Pharmaceutical Corp.* 225 F.3d 1349, 1355 (Fed. Cir. 2000) ("The first step in any invalidity analysis is claim construction, an issue of law that this court reviews *de novo*"); *Key Pharmaceuticals v. Hercon Labs. Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998) ("not unlike a determination of infringement, a determination of anticipation, as well as obviousness, involves two steps. First is construing the claim, a question of law for the court, followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art.")

[3] Gen-Probe's summary judgment motion notes that "the terms of the license impose obligations only upon those products of Gen-Probe that would constitute an infringement of the '338 patent but for the license." Memorandum of Points and Authorities in Support of Plaintiff Gen-Probe Incorporated's Motion for Partial Summary Judgment at 2 n.2 (attached as Banks Decl. Exhibit B).

The same is true with respect to Gen-Probe's unenforceability allegations. The question of the materiality of alleged misrepresentations or omissions is resolved with reference to the scope of the invention claimed. *See* 37 C.F.R. 1.56; *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1457 (Fed. Cir. 1984) (resolving issues of inequitable conduct requires reference to the claims of the patent).

A dramatic waste of judicial resources (as well as the time and resources of the parties, witnesses, and the jury) would result if the validity and enforceability issues were tried based on a construction of the claims of the '338 patent that was later reversed by the Federal Circuit. If these issues were tried and the Federal Circuit were to subsequently construe the claims more broadly, the trial of the validity and enforceability issues will have been for naught – and these issues would have to be tried anew. Moreover, fact discovery is still ongoing in this case, and expert discovery has yet to begin. Trial is over six months away. To the extent the parties may narrow their discovery and restrict their theories of the case as a result of this Court's claim construction, a different construction by the Federal Circuit may well require further fact discovery and additional expert discovery beyond that which would be needed if this Court's claim construction were upheld.

Rather than risk duplicative discovery and the possibility of a trial that would be rendered meaningless should the Federal Circuit have a different claim construction, it would be far more efficient to obtain appellate review now, prior to trying the remaining issues of the case.[4] Indeed, the very issue of efficiency was recognized by Judge Rader, of the Court of Appeals for the Federal Circuit, sitting by designation as the trial judge in *Loral Fairchild Corp. v. Victor Co.*, 931 F. Supp. 1044 (E.D.N.Y. 1996), *aff'd* 181 F.3d 1313 (1999). In *Loral*, Judge Rader directed entry of final judgment under Rule 54(b) of his own judgment of noninfringement, holding that

> [T]his court's claim construction drove the resolution of the issues between Sony and Loral. Claim construction impacted significantly on this court's conclusions on literal and equivalents infringement on both patents. Currently, the Federal Circuit does not defer to trial

[4] Claim construction is a matter of law that the Federal Circuit reviews *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

> court judgments on claim construction. . . . Thus, the Federal Circuit may adopt a different view of the claims at issue. With a number of trials remaining, the Federal Circuit's guidance on the proper scope of the claims will clarify the parties' rights and obligations under the patents and may lead to a substantial savings of time and expense.

Loral, 931 F. Supp. at 1047-48 (citations omitted). Although *Loral* involved multiple parties rather than multiple claims for relief, Judge Rader's rationale for entry of judgment under Rule 54(b) is equally applicable to this case.

C. The Remaining Counts Are Separable from the Adjudicated Counts

The Supreme Court has held that in deciding whether there are no just reasons for delay, a district court may consider whether the adjudicated counts are separable from the counts yet to be decided, and whether the nature of the adjudicated counts is such that the appellate court would not have to decide the same issues more than once. *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1 (1980). Here, the remaining counts are separable, and failure to obtain a prompt determination of the proper scope of the claims is more likely to result in multiple reviews of the same issues by the appellate court.

Apart from the fundamental issue of claim construction, Gen-Probe's invalidity and unenforceability counts are legally and factually distinct from its noninfringement count. While the noninfringement issue was resolved by comparing Gen-Probe's HIV/HCV test with the construed claims, resolving the invalidity Count II will require comparing the claims against the prior art. The unenforceability Counts V and VI will require examining the actions of the patent owner during the prosecution of the '338 patent. Because these counts do not share common legal or factual bases with the adjudicated issue of noninfringement (other than the core issue of claim construction), they are properly separable from the noninfringement count.

The case is even clearer for Gen-Probe's Count IV for unfair competition. This cause of action, brought under California law, is based solely on Vysis' actions *subsequent* to the issuance of the '338 patent. Moreover, Gen-Probe only asserts Vysis' knowledge of the purported invalidity and unenforceability of the '338 patent as the predicate for its unfair competition claim – the presence or absence of infringement has nothing to do with this count. Accordingly, the unfair competition count is similarly separable from the noninfringement count.

II. A Stay of Proceedings on the Remaining Counts is Appropriate

As demonstrated above, the Federal Circuit's *de novo* claim construction will settle the fundamental issue upon which the remainder of this case will rest. So that the Court and the parties may conserve their resources and otherwise avail themselves of the efficiencies created by an immediate appeal to the Federal Circuit, the Court should stay proceedings on Gen-Probe's remaining counts pending appellate review.

Gen-Probe cannot complain of prejudice in connection with the requested stay. If Gen-Probe is correct in the claim construction it has persuaded the Court to adopt, the most expeditious way of getting a final resolution of its obligations under the '338 license is to have the claim construction issue promptly reviewed by the Federal Circuit.

Finally, there is ample precedent for the requested stay. *See, e.g., Trilogy Comms. Inc. v. Times Fiber Comms., Inc.*, 109 F.3d 739 (Fed. Cir. 1997), in which the Federal Circuit noted that

> having resolved the infringement claim, the [district] court certified the summary judgment of non-infringement as an appealable final judgment pursuant to Fed. R. Civ. P. 54(b). The court stayed further proceedings on Times Fiber's counterclaims, including its claim for a declaratory judgment of patent invalidity and unenforceability.

Id. at 741.

III. Conclusion

For the foregoing reasons, no just reason for delay exists. Accordingly, entry of final judgment as to Counts I and III of Gen-Probe's Second Amended Complaint is appropriate.

Dated: June 29, 2001

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